

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

A double blinded clinical trial for evaluation of oral memantine and placebo in acute postoperative pain in patients undergoing dacryocystorhinostomy

Protocol summary

Summary

Objectives: Acute pain control after surgery is a crucial fact in health management. Memantine is a N-Methyl-D-aspartate (NMDA) antagonist which is a leading drug for Alzheimer's disease treatment. Design: In this double blind randomized clinical trial, 60 patients candidate for dacryocystorhinostomy are assigned. Choosing envelope number 1 or 2, patients are randomly allocated to memantine or placebo group. Patients, anesthesiologist and the statistician are blinded to the assignments. This clinical trial is in phase 2 / phase 3. Setting and conduct: General anesthesia will be carried out with fentanyl 2 micro gram per kilogram, midazolam 0.12 milligram per kilogram, sodium thiopental 5 milligram per kilogram and atracurium 0.5 milligram per kilogram. After tracheal intubation anesthesia will be maintained with propofol 100 micro grams per kilogram per minute Major inclusion and exclusion criteria: Participants with written consent form and without any serious cardiovascular, respiratory, renal, liver, cerebral disease and addiction are included in the study. Patients whom do not meet all the above criteria are excluded. Intervention: Oral memantin 40 mg (exir darou, Iran) or placebo (flour tablet) will be administered to the patients in each group at entrance to the operation room and before anesthesia. Main outcome measurements: Visual analogue scale and ramsey scale will be used immediately, 1, 2 and 6 hours after surgery, for the measurement of pain and sedation score, respectively. Data will be recorded and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011810599N5**
Registration date: **2017-01-05, 1395/10/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-05, 1395/10/16

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

p-rahimzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran university of medical sciences, Faculty of research

Expected recruitment start date

2016-07-30, 1395/05/09

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blinded clinical trial for evaluation of oral memantine and placebo in acute postoperative pain in patients undergoing dacryocystorhinostomy

Public title

Effects of memantine in Dacryocystorhinostomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with written informed consent; without serious cardiovascular, respiratory, renal, liver, cerebral disease and addiction; 18-65 years age.

Exclusion criteria: not meeting all the inclusion criteria

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran university of medical sciences, Hemmat Expressway, Tehran

Street address

Hemmat Expressway, Tehran

City

Tehran

Postal code**Approval date**

2016-06-01, 1395/03/12

Ethics committee reference number

27356

Health conditions studied**1****Description of health condition studied**

acute post operative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes**1****Description**

pain score

Timepoint

at the end of the surgery (0) and 1, 2 & 6 hours after surgery

Method of measurement

visual analogue scale and ramsey scale

Secondary outcomes**1****Description**

Pain killer number

Timepoint

after operation (0) and 1, 2 & 6 hours after surgery

Method of measurement

number of pain killer used and recorded in questionnaire

Intervention groups**1****Description**

intervention group: Patients will receive 40 milligrams of oral memantin (Exir darou,Iran) at the entrance to the operating room. Then the patients will receive induction for anesthesia.

Category

Treatment - Drugs

2**Description**

Control group: Patients will receive flour tablets at the entrance to the operating room. Then the patients will receive induction for anesthesia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Eye operating room, Hazrat Rasul Medical Complex, Sattar khan Ave. , Tehran

Full name of responsible person

Dr Poupak Rahimzadeh

Street address

Sattar khan ave. , Hazrat Rasul Medical complex, Tehran

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Iran University of Medical Sciences, Hemmat expressway, Tehran

Full name of responsible person

Dr Mohammad Musavi

Street address

Hemmat expressway, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research Iran University of Medical Sciences, Hemmat expressway, Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences, Hemat expressway, Tehran

Full name of responsible person

Dr Hamidreza Faiz

Position

Associate professor

Other areas of specialty/work

Street address

Hazrat Rasul Medical complex, Sattar khan Ave. , Tehran

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

hrfaiz@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences, Hemmat expressway, Tehran

Full name of responsible person

Dr Poupak Rahimzadeh

Position

Associate professor

Other areas of specialty/work

Street address

Hazrat Rasul Medical complex, Sattar khan Ave. , Tehran

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

p-rahimzadeh@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences, Hemmat Expressway, Tehran

Full name of responsible person

Dr Poupak Rahimzadeh

Position

Associate professor

Other areas of specialty/work

Street address

Hazrat Rasul Medical complex, Sattar khan Ave. , Tehran

City

Tehran

Postal code

Phone

+98 21 6435 2326

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

